

**Docket No.: TJU0001-107  
PATENT**

**Serial No.: 10/621,684  
Filed: July 17, 2003**

### **REMARKS**

#### **Status of the Claims**

Claims 23-44 are in the application.

Claims 23-44 have been rejected.

By way of this amendment, claims 24 have been canceled, claims 23 and 42 have been amended.

Upon entry of this amendment, claims 23, 25-28, 30-34, 36 and 38-47 will be pending.

#### **Summary of the Amendment**

Claim 23 has been amended to specifically recite that the ST receptor binding ligand is a peptide. Support for this amendment is found throughout the specification, such as for example on pages 6.

Claims 24 has been canceled as redundant with claim 23 as amended.

Claim 42 has been amended to specifically recite that the ST receptor binding ligand is a peptide. Support for this amendment is found throughout the specification, such as for example on pages 6.

The claims as amended read on the previously elected species.

#### **Rejection under 35 U.S.C. §112, first paragraph**

Claims 23, 28, 30-31, and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It is asserted that the ST receptor binding ligands set forth in the claims are not limited to peptides. It is asserted that the specification contains no examples of non-peptides. It is asserted that the specification has not sufficiently described possession of compounds other than peptides.

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Applicant respectfully disagrees. The specification clearly describes the invention such that those having ordinary skill in the art would recognize that Applicant was in possession of the claimed invention at the time the application was filed. It is clear from the specification that Applicant was in possession of ST receptor ligands at the time the application was filed. The specification provides adequate disclosure for compliance with the written description requirements. However, in an effort to advance prosecution, Applicant has amended claims 23 and 42 to limit the ST receptor ligands to those that are peptides.

Applicant respectfully request that the rejection of claims 23, 28, 30-31, and 41-42 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement be withdrawn.

#### **Double Patenting Rejections**

Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,060,037.

Applicants urge that the claims in U.S. Patent No. 6,060,037, are exclusively directed at separate and distinct inventions as set forth in the Restriction Requirement issued in the instant application on October 1, 2004. That restriction requirement indicated that the claims in the application contained seven groups of patentably distinct inventions. According to the Official Action that contained the restriction requirement, because the several inventions were distinct, restriction was proper and Applicants were required to elect a single invention for examination.

Applicants elected Group I which embraces compositions of matter as a separate and distinct invention from those directed at imaging methods, treatment methods and gene therapy methods. Each of the pending claims in the present application is directed to compositions of matter.

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The claims in U.S. Patent No. 6,060,037 are directed at methods of imaging colorectal tumors, in vitro methods of screening individuals for metastatic colorectal cancer, in vitro methods of determining a tumor cell is colorectal tumor cell, methods of treating colorectal tumors, methods of delivering nucleic acid molecules to cell and kits for determining whether a sample contains a colorectal cancer cell. The invention claimed in the 037 Patent corresponds to non-elected groups in the present application.

U.S. Patent No. 6,060,037, and the present application are related to each other. The application which issued as U.S. Patent No. 5,518,888 is the parent. The application which issued as U.S. Patent No. 5,879,656 was a continuation in part of the application which issued as U.S. Patent No. 5,518,888. The present application is a continuation of an abandoned application which was a continuation of the application that issued as U.S. Patent No. 5,879,656. The application which issued as the 037 Patent was a US National stage application which claimed priority as a continuation-in-part to the application that issued as U.S. Patent No. 5,518,888. The applications are clearly members of the same family.

None of the claims from U.S. Patent No. 6,060,037 cited as rendering the claims of the present application unpatentable for obvious-type double patenting could have been prosecuted in the present application upon the election of Group I. The restriction requirement makes clear that the subject matter of the cited claims in each instance was that of a separate and patentably distinct invention. A finding that the claims are obvious in view of the cited claims is completely contrary and inconsistent with the position taken by the Office in requiring restriction.

The presently claimed invention encompasses compositions of matter. The claims cited as rendering the present claims unpatentable are directed to imaging methods, treatment methods and gene delivery methods, which each correspond to subject matter deemed by the patent office as being separate and patentably distinct subject matter. The Office has deemed that the composition claims are patentably distinct from the various cited method claims

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(which themselves have been deemed separate and patentably distinct from each other). There is no question or ambiguity that each pending claim is a composition claim and each cited claim is a method claim. The Office has deemed these inventions to be separate and patentably distinct inventions. Accordingly, the rejection of obviousness-type double patenting with respect to U.S. Patent No. 6,060,037 should be withdrawn.

Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,962,220.

Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,087,109.

Claims 23-25, 28-32, 35-56, 41-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 10, 32, 37, 9, 41-42, 54-55, 58, 63-64, 92, 96-97, 99, 102, 108, 109, 114, 116, 118-119, 125-153 of copending Application No. 08/468,449.

At this time, no claims have been indicated to be allowable if the double patenting rejections were overcome. It is therefore premature to file a terminal disclaimer. If determined to be appropriate based upon the subject matter of the rejected claims, Applicant would file such a terminal disclaimer upon indication that claims would be otherwise allowable.

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**Conclusion**

Claims 23, 25-28, 30-34, 36 and 38-47 are in condition for allowance. An indication of allowability is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at 215-665-5592 to clarify any unresolved issues raised by this response. Upon an indication of allowability, Applicant will promptly file terminal disclaimers as appropriate by telefacsimile to advance the claims to allowance and grant.

As indicated on the transmittal accompanying this response, the Commissioner is hereby authorized to charge any debit or credit any overpayment to Deposit Account No. 50-1275.

Respectfully submitted,



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Date: April 7, 2006  
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